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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,077	02/12/2002	Thomas R. Gadek	9491-058-27	3125

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GENENTECH, INC.  
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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/073,077

Applicant(s)

GADEK ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

S-20

## **DETAILED ACTION**

### **Status of the claims**

The amendment filed July 14, 2005 is acknowledged and has been entered.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 25-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim recites " a method for identifying compounds that bind a target of interest whereas the body of the claim merely recites detecting the non-covalent binding of the compound to the target by mass spectrometry. Does the detecting of the compound to the target identify the compound?

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 25, 26, 28 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffey et al. (US 6,770,486).

Griffey et al disclose methods of identifying compounds that bind to a target of interest. Griffey et al disclose sets of ligands that are screened to determine ligands that non-covalently bind to a target molecule. Griffey et al disclose selecting ligands from the sets and chemically linking the ligands to form a compound. Griffey et al disclose that the two ligands can be concurrent ligands which bind to distinct sites on the target molecule. Griffey et al disclose that the compound formed by linking the first ligand and second ligand has a greater affinity for the target molecule than either first or second ligand. Griffey et al disclose detecting the binding of the compound to the target molecule by mass spectrometry. Griffey et al disclose that the target molecule can be RNA, DNA, proteins and polysaccharides.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1641

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffey et al in view of Wells et al (WO 00/00823).

See above for the teachings of Griffey et al.

Griffey et al differ from the instant invention in failing to specifically teach the first binding site is the same as the second binding site. Griffey et al also fail to specially teach the disassociation constant equal to 500 uM or less.

Wells et al disclose two ligands linked together to bind to two binding sites on a target biomolecule (p. 22). Wells et al disclose that these ligands have non-covalent affinity for the site of interest (p. 15). Wells et al disclose that linked ligands can bind to the target biomolecule comprising two binding sites that are the same. Wells et al discloses that each member of the linked conjugate can be from the same class.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use linked ligands comprising ligands from the same class to bind to two sites on a target biomolecule that are the same because Wells et al shows that target biomolecules comprise two sites that are the same and Wells et al shows that using ligands from the same class allows for linked ligands that have non-covalent affinity for the site of interest and thus allows for new small drug leads (p. 3).

With respect to the dissociation constant as recited in the instant claims. Although Griffey et al fails to specifically teach the dissociation constant equal to 500  $\mu$ M or less. Griffey et al does disclose that the selection of a dissociation constant is compared to a standard and selected accordingly (col 16). The optimal dissociation constant of the ligands can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of *Aller*, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation."

Art Unit: 1641

Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

9. Claims 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffey et al in view of Hajduk et al. (J. Am. Chem. Soc. 1997, 119, 5818-5827).

See above for the teachings of Griffey et al.

Griffey et al differ from the instant invention in failing to specifically teach the protein is matrix metalloproteinase stromelysin.

Hajduk et al disclose the use of stromelysin to design compounds made of first and second ligands that are linked together that bind to stromelysin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use stromelysin as a target molecule as taught by Hajduk et al into the method of Griffey et al because Griffey et al is generic with respect to the protein target molecule to be used to determine binding ligands and one would use the appropriate reagent, i.e. stromelysin to determine the desired binding ligands, in this case ligands which bind to stromelysin.

10. Claims 31 and 32 rejected under 35 U.S.C. 103(a) as being unpatentable over Griffey et al in view of Ellman (WO 99/49314).

See above for the teachings of Griffey et al.

Griffey et al differ from the instant invention in failing to specifically teach the protein is a cytokine receptor such as erythropoietin.

Ellman disclose the use of erythropoietin (p. 17) to determine if crosslinked ligands bind to erythropoietin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use erythropoietin as a target molecule as taught by Ellman into the method of Griffey et al because Griffey et al is generic with respect to the protein target molecule to be used to determine binding ligands and one would use the appropriate reagent, i.e. erythropoietin to determine the desired binding ligands, in this case ligands which bind to erythropoietin.

11. Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffey et al in view of Erlanson et al (US 6,919,178).

See above for the teachings of Griffey et al.

Griffey et al differ from the instant invention in failing to specifically teach the protein is protein tyrosine phosphatase 1b (PTP1b).

Erlanson et al disclose target biomolecules which can be used to determine ligands which can bind to sites on the target biomolecule. Erlanson et al disclose that the target biomolecule can be protein tyrosine phosphatases such as PTP1b.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use PTP1b as a target molecule as taught by Erlanson et al into the method of Griffey et al because Griffey et al is generic with respect to the protein target molecule to be used to determine binding ligands and one would use the appropriate reagent, i.e. PTP1b to determine the desired binding ligands, in this case ligands which bind to PTP1b.



***Response to Arguments***

12. Applicant's arguments with to claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gary Counts  
Examiner  
Art Unit 1641  
September 8, 2005

  
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09/14/05